K061962
p1/2

Attachment 3

510(k) Summary

Date: April 19, 2006

Submitter:

Ethox International, Inc.
251 Seneca Street
Buffalo, New York USA 14204-2088
Tel: 716-842-4000
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John Riggi, VP of Quality Assurance & Regulatory Affairs
riggi@ethoxint.com

JUL 25 2006

Device Name: **SURGI-CUF® *REUSABLE* Blood Pressure Cuffs**

Common/ Usual Name: Blood Pressure Cuff

Product Code/ Classification: DXQ / 21CFR870.1120

Intended Use: Indirect measurement of blood pressure

Indications for Use: The SURGI-CUF® *REUSABLE* Blood Pressure Cuff is a bladder and tube set for use in conjunction with a variety of blood pressure monitoring systems for determination of a persons blood pressure. The device is non-sterile and reusable.

Device Description: The Ethox SURGI-CUF® *REUSABLE* Blood Pressure Cuffs consists of an integrated inflatable cuff bladder manufactured from Urethane coated nylon. The cuff is closed with a hook and loop fastening system (Loop with vinyl backing and Vinyl Hook). The Ethox SURGI-CUF® *REUSABLE* Blood Pressure Cuffs are reusable, non-sterile and latex free. Attached to the end of each PVC tube are a variety of connectors (PVC, ABS or Nylon) for use with most monitoring systems.

Ethox SURGI-CUF® *REUSABLE* Blood Pressure Cuffs are available in the following configurations:

- Six sizes (Child, Sm. Adult, Adult, Adult Long, Large Adult, Thigh)
- Single Tube configuration with 6 types of connectors
- Double Tube configuration with 2 types of connectors

Predicate Devices:

The SURGI-CUF® *REUSABLE* Blood Pressure Cuff is substantially equivalent to the following predicate devices:

K022482; Sensa-Cuff; GE Medical Systems Information Technologies

Preamendent; CRITIKON DURA-CUF®; Critikon Company, LLC.

K040286, SURGI-CUF®; Ethox Corporation

The SURGI-CUF® *REUSABLE* Blood Pressure Cuff has the same intended use and general construction as the predicate devices. All four devices contain a bladder and hook & look fastening system. The SURGI-CUF® *REUSABLE* and DURA-CUF® are made of the same material. The SURGI-CUF® REUSABLE and SURGI-CUF® are available in the same sizes.

Performance:

Bench and laboratory testing to demonstrate safety and effectiveness per:

- AAMI SP10:2002, Manual, electronic or automated sphygmomanometers
- AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing User Validation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2006

Ethox International, Inc.
c/o Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Service NA, Inc.
2307 East Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K061962
Trade Name: SURGI-CUF® *REUSABLE* Blood Pressure Cuffs
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: July 11, 2006
Received: July 12, 2006

Dear Mr. Devine:

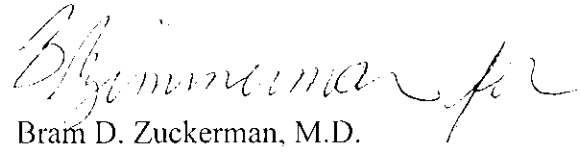
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061962

Attachment 2

Statement of Indications for Use

Device Name: SURGI-CUF® *REUSABLE* Blood Pressure Cuffs

Indications for Use: The SURGI-CUF® *REUSABLE* Blood Pressure Cuff is a bladder and tube set for use in conjunction with a variety of blood pressure monitoring systems for determination of a persons blood pressure. The device is non-sterile and reusable.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061962